UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,793	06/26/2001	David J. Ecker	IBIS-0368	1490

34138 7590 08/26/2003

COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1631	18

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/891,793	Applicant(s) ECKER ET AL.	
	Examiner Ardin Marschel	Art Unit 1631	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2003 and 19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25* is/are rejected.

7)☒ Claim(s) *22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 1/23/03 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election of Group IV (claims 17-25) in Paper No. 12, filed 1/23/03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an electionn without traverse (MPEP § 818.03(a)).

VAGUENESS AND INDEFINITENESS

Claim 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, line 2, the step of identification is set forth which is reasonably interpreted as an action. Then in lines 2-5, the phraseology is set forth as "comprising a recommended pair of primers..." which is a composition. This causes the claim to be vague and indefinite as to whether an action is meant or a composition, or, alternatively, as to how an action can comprise a composition. What actual action is meant? Clarification via clearer claim wording is requested. Claims dependent directly or indirectly form claim 19 also contain this issue due to their dependence.

NOT FURTHER LIMITING CLAIM

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 19 and 20 are directed to utilizing primers for nucleic acid bioagent identification which reasonably limits the bioagent practice therein to nucleic acids. Claim 22 depends from claim 20 and 19, indirectly, and cites generic bioagent practice therein which is broader than the bioagent being a nucleic acid as in the claims from which it depends. This broader bioagent citation broadens rather than further limits the claim practice and thus supports this objection.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17 and 18 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Tang et al. (P/N 6,393,367).

Tang et al. Discloses the identification of an unknown biological molecule (a bioagent as instantly claimed) via mass data comparison as summarized in the abstract. The abstract also summarizes the computing of a score regarding the probability that the identification is incorrect. In columns 3-4 this is again summarized as well as listing several bioagents, or selected fragments (instant claim 18) thereof, for identification. A user may browse for a protein, for example, as disclosed in column 5, lines 24-33, or use the system for scoring etc. as described in column 11, lines 39-47. Example output

which is returned to user of scored information is shown in Figure 2. In column 5, lines 5-57, master databases for various bioagents are disclosed including complicated structures that may be utilized therein which anticipates the instant dimensional limitation of such master databases. The limitation of "master" database is reasonably interpreted as a database which contains a compilation of a variety of information; such as molecular mass, etc. as also instantly claimed; from which to compare an unknown's information. Column 5, line 58, through column 8, line 11, describe interrogating algorithms and software for comparing an unknown bioagent's data with various databases. These disclosure anticipate the basic generic invention as instantly claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Margery et al. (P/N 6,055,487) or Coli et al. (P/N 6,018,713) taken in view of either of Muddiman et al. [Analytical Chem. 69:1543-1549 (1997)] or Muddiman et al. [Analytical Chem. 68:3705-3712 (1996)].

Both of the descriptions in Margery et al. and Coli et al. are directed to the interactive ordering of testing at a central laboratory with computer network return of the test results as summarized in their respective abstracts and titles. Coli et al. In column 3, lines 1-5, lists tests available including microbiology. In lines 6-10, of Coli et al. a user may retrieve the test information. The Internet and other networks are summarized in Coli et al. in column 9, lines 62-67, for use in communicating test results. LAN, WAN, and Internet communication of test data is also described in Margery et al. in column 6, lines 44-59. Various medical testing types are summarized as being useful regarding laboratory testing in the invention of Margery et al. in column 2, lines 59-63, directed to microbiology testing. In summary, both Margery et al. and Coli et al. describe central laboratory testing inclusive of microbiology testing which in a medical context motivates and suggests testing for microorganisms in medical samples. Both also describe the communication of test results over networks such as the Internet etc. Specific testing procedures, however, for microorganisms has not been set forth in these references and thus must be found in related prior art.

The two Muddiman et al. references, cited above, both describe the usage of PCR with mass spectrometry for microorganism detection in samples. Both references utilize recommended PCR primer sets for hybridizing to flanking sequences to a targeted region of the nucleic acid to be detected as summarized in the respective abstracts. Figures 2 and 3 on page 3709 of the second Muddiman et al. reference shows the characteristics of mass fragment spectra for at least two microorganisms which thus is at least a minimal dimensional master database of such masses for

identification purposes thus providing a reasonable expectation of success for such identification. Table 1 on page 3710 shows distinctive mass database values for 4 different microorganisms. A specific statement of taxonomic differentiation and thus identification is set forth in the second Muddiman et al. reference on page 3708, first column, last sentence of the second full paragraph, which clearly sets forth the recognition of such differentiation practice for identification of one microorganism from another.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to be motivated to performed central laboratory testing for various medical issues including microbiology testing as set forth in Margery et al. or Coli et al. where the testing procedures usable in such a laboratory microorganism testing methodology is set forth in either of the above listed Muddiman et al. references including a reasonable expectation of success for identifying microorganisms thereby thus resulting in the practice of the instant invention.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 25, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER